

JUL 07 2000

KOD1912  
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510(k) SUMMARY AS REQUIRED BY SECTION 807.92(C)

Submitted by: Mrs. Mitsuko Yoneyama  
President

Narishige Co., Ltd.  
27-9, Minamikarasuyama 4-chome  
Setagaya-ku  
Tokyo 157-0062  
Japan

Phone: 81-3-3308-8383  
Fax: 81-3-3308-8700  
E-mail: sales@narishige.co.jp

Date Submitted: June 20, 2000

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FDA/CDRH/ODE/HAC

Device Identification:

Trade Name: IM-9B Microinjector  
Common Name: Microinjector  
Classification Name: Assisted Reproduction Micromanipulators and  
Microinjectors (21 CFR, 884.6150)

Predicate Device:

Notice of Final Rule, 63 FR 48428, Docket number 97N-0335

Device Description:

The IM-9B Microinjector is used to inject solutions into organisms, aspirate fluid samples from tissues or hold cells and eggs by aspiration onto the end of a holding pipette. It is easy to use simply by turning the Control Knob clockwise for injection and counterclockwise for aspiration.

The IM-9B Microinjector is a component part of a micromanipulator system. For ICSI procedure using the IM-9B, the micromanipulator system requires:

- 1 unit of the manipulator mounting adaptor (for mounting the micromanipulators to the microscope);
- 2 units of the coarse manipulator (for coarse positioning);
- 2 units of the fine micromanipulator (for fine positioning);
- 2 units of the joint unit (for holding the pipette holder)
- 2 units of IM-9B Microinjector (one for holding pipette and one for injecting pipette);
- 1 holding pipette;
- and 1 injecting pipette.

Examples of roles the IM-9B plays in the ICSI would be:

- holding an oocyte
- aspirating a sperm into the injection pipette
- injecting a sperm into an oocyte

**Intended Use:**

The IM-9B Microinjector is used to inject solutions into organisms, aspirate fluid samples from tissues or hold cells and eggs by aspiration onto the end of a holding pipette.

**Substantial Equivalence:**

In accordance with the Final Rule on reclassification of Medical Devices Used for In Vitro Fertilization, Narishige Co., Inc. cites 63 FR 48428, Docket number 97N-0335 as support for substantial equivalence.

**Technological Characteristic:**

The IM-9B Microinjector is a manually operated oil hydraulic screw-driven microinjector.

The specification of the IM-9B is summarized in the table below.

Maximum Movement Range of the Plunger	53mm
The Distance the Plunger Travels by One Rotation of the Control Knob	500um
The Amount Controlled by One Rotation of the Control Knob	Approx. 10ul



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Mrs. Mitsuko Yoneyama  
President  
Narishige Co., Ltd.  
27-9 Minamikarasuyama 4-chome  
Setagaya-ku  
Tokyo 157-0062  
JAPAN

Re: K001912  
IM-9B Microinjector  
Dated: June 20, 2000  
Received: June 23, 2000  
Regulatory Class II  
21 CFR 884.6150/Procode: 85 MQJ

Dear Mrs. Yoneyama:

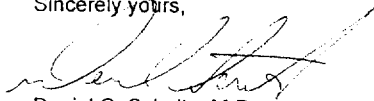
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Daniel G. Schultz, M.D.  
Captain, USPHS  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure(s)

1C 001912

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510(k) Number (if known): K001912

Device Name: IM-9B Microinjector

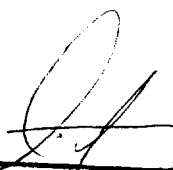
**Indications For Use:**

The IM-9B Microinjector is used to inject solutions into organisms, aspirate fluid samples from tissues or hold cells and eggs by aspiration onto the end of a holding pipette.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K001912

(Optional Format 3-10-98)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

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